IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT SPOKANE

BEAU ARMSTRONG, Plaintiff, v. ATRIUM MEDICAL CORPORATION; GETINGE AB; MAQUET CARDIOVASCULAR US SALES, LLC; Defendants.	NO. COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Beau Armstrong, by and through his undersigned counsel, alleges as follows:

INTRODUCTION

1. This case involves a synthetic mesh medical device, known as ProLite polypropylene mesh ("ProLite"), manufactured, promoted, marketed, distributed and sold by Defendants for use in hernia repair.

2. The ProLite mesh is a non-absorbable surgical mesh constructed of monofilaments of polypropylene.

3. Defendants misrepresented that ProLite is a safe and effective medical device for hernia repair. In fact, ProLite causes a litany of serious medical problems and complications, including, but not limited to, mesh shrinkage, deformation, material degradation, foreign body

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

reaction, chronic inflammation, mesh infection, migration, organ damage, nerve damage, chronic pain and sexual dysfunction.

4. Plaintiff brings this action to recover damages for injuries resulting from the strict liability, failure to warn, negligence, negligent misrepresentation, and breach of implied and express warranties by Defendants in the manufacture, promotion, marketing, distribution and sale of ProLite polypropylene mesh.

PARTIES

1. Plaintiff Beau Armstrong ("Plaintiff") is a resident of the State of Washington.

2. Defendant Getinge AB ("Getinge") is a Swedish corporation doing business in the United States. Getinge is a pharmaceutical company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including ProLite polypropylene mesh.

3. Defendant Atrium Medical Corporation ("Atrium") is a Delaware corporation headquartered in New Hampshire. Atrium is a wholly-owned subsidiary of Getinge. Atrium is a medical device company involved in the research, development, testing, manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including – at all times relevant hereto – ProLite polypropylene mesh. In 2011, Atrium was acquired by Getinge in a transaction which involved, *inter alia*, the transfer of all Atrium's liquid assets to Getinge and the effective dissolution of Atrium's board of directors. After being acquired by Getinge, Atrium ceased to file annual reports with the State of New Hampshire, causing its authority to transact business therein to be suspended. Getinge thereupon applied for requalification to conduct business in New Hampshire using Atrium's corporate name. Following Getinge's acquisition of Atrium, Getinge controls the activities of Atrium and is the direct employer of the individuals formerly employed by Atrium.

4. Defendant Maquet Cardiovascular US Sales, LLC ("Maquet Cardiovascular") is a Delaware corporation headquartered at 45 Barbour Pond Drive, Wayne, New Jersey. Maquet Cardiovascular is a pharmaceutical company involved in the research, development, testing,

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

manufacture, production, distribution, marketing, promotion and/or sale of medical devices used for hernia repair, including – at all times relevant hereto – ProLite polypropylene mesh. Maquet is a wholly owned subsidiary of Getinge and is the exclusive distributor of all surgical mesh products manufactured by Defendants. Maquet Cardiovascular has four members:

a. Stephanie Trizinski, a citizen of the State of New Jersey;

b. Jennifer Paradise, a citizen of the State of New Jersey;

c. John McPartlin, a citizen of the State of New Jersey; and

d. Datascope Corp., a Delaware corporation headquartered in New Jersey.

JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. section 1332. Plaintiff is a citizen of a state different from Defendants and the amount in controversy, exclusive of interest and costs, exceeds $75,000.

2. This Court has personal jurisdiction over each defendant because each Defendant purposefully directed its marketing, sales and distribution of numerous pharmaceutical and/or healthcare products to Washington. Each Defendant has substantial contacts with Washington such that maintenance of this action is consistent with traditional notions of fair play and substantial justice.

3. Venue is proper in this Court pursuant to 28 U.S.C. section 1391(b). Each Defendant is a resident of this district, does business in this district, is subject to personal jurisdiction in this district, and a substantial part of the events giving rise to the claims set forth in this Complaint occurred in this district.

FACTUAL BACKGROUND

POLYPROPYLENE MESH

1. Hernia, a condition affecting thousands of men and women in the United States each year, is the protrusion or projection of an organ or tissue through the wall that normally contains it. Although a hernia may form in any part of the abdominal wall, the most common site

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

is the groin. Groin hernias are known as inguinal or femoral, depending on the location of the hernia.

2. Until 1958, abdominal wall hernias were repaired without mesh. In 1958, Dr. Frances Usher published a medical journal article entitled *Marlex mesh, a new plastic mesh for replacing tissue defects*. Dr. Usher used polypropylene mesh in experimental canine work for abdominal repair. Polypropylene is a petroleum-based plastic initially used in the Hula-Hoop and for kitchen storage applications.

3. Heavily promoted by the medical device manufacturers, including Defendants, hernia mesh, typically made wholly or partly of polypropylene, is commonly used in hernia repair surgery.

4. It has been known since 1953 that any implanted device must not be physically modified by tissue fluids, be chemically inert, not incite an inflammatory or foreign body cell reaction, be non-carcinogenic, not produce allergic reactions, and be able to withstand mechanical stress. D. Ostergard, *Degradation, Infection and Heat Effects on Polypropylene Mesh for Pelvic Implantation: What Was Known and When it Was Known*, 22 INT'L UROGYNECOLOGY J. 771-774 (2011).

5. Polypropylene is not biologically inert in the human body, and can cause serious injury to patients, significantly impacting their quality of life. As one author stated, "[p]rosthetic meshes are … not the inert materials they are claimed to be and can expand as well as shrink." A. Coda, *Structural Alterations of Prosthetic Meshes in Humans*, 7 HERNIA 29-34 (2003).

6. A typical response to mesh implanted in the human body is inflammation, granuloma formation and a foreign body reaction. Scar tissue forms around the implant and causes contraction of the mesh up to 50%. This inflammation, foreign body response and scar tissue formation is a permanent condition and can result in long-term complications. U. Klinge et al., *Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias,* 165 EUR. J. SURGERY 665-73 (1999).

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

7. Despite the promotion of mesh as safe and effective by Defendants, the published medical literature contradicts this unsupported belief. One author observed that "[t]he literature suggests otherwise with reports of various degrees of degradation, including depolymerization, cross-linking, oxidative degradation by free radicals, additive leaching, hydrolysis, stress cracking and mesh shrinkage along with infection, chronic inflammation and the stimulation of sclerosis." The author concluded, "Based on available evidence the polypropylene used for surgical treatment of various structural defects is not inert after implantation in the human body." G. Sternschuss et al., *Postimplantation Alterations of Polypropylene in the Human*, 188 J. UROL. 27-32 (2012). As the mesh degrades in the human body, small flakes of polypropylene can lead to infection and irritation, and resultant serious pain, as the body tries to rid itself of the foreign material.

8. Once implanted, mesh contracts as well as cracks substantially in the human body. In one study, a contracture rate of 30% to 50% was found four weeks after implantation. Another study reported an 85% contracture rate after eight years. Nerve fibers are entrapped in the contracted tissue causing severe pain.

9. A debilitating consequence of hernia repair with mesh is inguinodynia, or chronic groin pain. This condition results from nerves, such as the ilioinguinal, iliohypogastric and genitofemoral nerves, coming into contact with mesh, after its degradation and deformation in the body following implantation, and from the persistent and permanent foreign body reaction to the implantation of mesh. It has been reported that hernia repair with mesh results in an extraordinarily high rate of inguinodynia – in some reports approaching 50%. *See, e.g.*, J.E. Fischer, *Hernia Repair: Why Do We Continue to Perform Mesh Repair in the Face of Human Toll of Inguinodynia?* 206 AMER. J. SURG. 619-23 (2013).

10. Other studies have found an even higher rate of chronic pain after hernia repair with mesh. One study found that approximately 75% of patients had pain one year after hernia repair at rest, and 78% had pain when moving. B. Page, *Pain from Primary Inguinal Hernia and the Effect of Repair on Pain,* 89 BRIT. J. SURG. 1315-18 (2002).

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

DEFENDANTS' PROLITE MESH

1. On December 16, 1993, Atrium received notification from the FDA that the 510(k) submission for Atrium Polypropylene Monofilament Mesh had been approved, finding the device to be substantially equivalent to a pre-MDA device or another device which had been granted clearance under 510(k). The granted clearance (K930669) applied to the product the specifications of which had been transmitted to the FDA for review, namely a flat, low-profile polypropylene monofilament surgical mesh which was later commercialized under the trade name ProLite.

2. Around 2003, Atrium was notified by its polypropylene supplier that it would no longer be supplying polypropylene to customers using the polymer for applications involving permanent human implantation.

3. Thereupon, Atrium began evaluating replacement polypropylene resins by conducting a variety of tests on candidate polypropylene samples.

4. Among the polymers nominated to replace the polypropylene Atrium used at the time the ProLite was cleared by the FDA was a resin called Profax-6523 manufactured by a Dutch company called LyondellBasell.

5. Of all of the samples which Atrium tested, Profax-6523 was the only polypropylene resin which did not contain any antioxidant additives.

6. In 2005, Atrium issued an Engineering Change Order to begin manufacturing ProLite using Profax-6523 despite the fact that it lacked antioxidants and despite LyondellBasell's admonition that Profax-6523 was not approved for applications involving permanent human implantation.

7. Atrium made this significant change to the base material of the ProLite without obtaining supplementary clearance pursuant to Section 510(k) of the Food Drug and Cosmetic Act (FDCA), making the ProLite misbranded pursuant to 21 U.S.C. 352(o) and adulterated pursuant to 21 U.S.C. 351(f)(l)(B).

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

8. While it is typical for polypropylene used in medical applications to contain anti-oxidant additives to prevent oxidative degradation *in vivo*, ProLite's construction from Profax-6523, which completely lacks such anti-oxidants, makes it unreasonably susceptible to oxidative degradation.

9. Atrium was aware that its chosen polypropylene lacked antioxidants when it elected to move forward manufacturing ProLite with said polypropylene formulation.

10. Atrium performed tests demonstrating that such polypropylene formulation oxidized and degraded faster than polypropylene which had been stabilized with antioxidant additives.

11. Degraded polypropylene substantially raises the risk of infection, chronic pain, mesh contracture, meshoma, and mesh migration.

12. The ProLite contains a number of design elements which render the product unreasonably dangerous to the patient, including but not limited to the following:

a. The heavyweight, small-pore construction of ProLite results in a high volume of non-asborbable synthetic polypropylene material in the patient's soft tissue, increasing the magnitude of the host inflammatory response and – as a result – the risk of chronic pain, the risk and rate of harmful polypropylene degradation, and mesh contracture; and

b. The unstabilized polypropylene base material results in a drastically increased risk of infection, mesh erosion, chronic pain, excessive scarring, contracture, and meshoma as a result of *in vivo* degradation.

13. Despite the abundance of scientific and medical information published in the literature relating to the dangerous properties and serious risks of polypropylene mesh, Defendants made a deliberate decision to ignore these dangers and to aggressively promote ProLite polypropylene mesh to healthcare providers and consumers. Defendants misrepresented and concealed from Plaintiff, Plaintiff's physicians and consumers, the serious risks, dangers and defects enumerated in this Complaint.

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

PLAINTIFF FACTUAL ALLEGATIONS

1. Plaintiff Beau Armstrong was 41 years old when he underwent parastomal hernia repair surgery by Dr. Kevin Robertson on January 12, 2018 at Providence St. Peter Hospital in Olympia, Washington. During the procedure, Plaintiff's surgeon implanted a ProLite mesh, Catalog number 1000306-00; Lot number 418997. The mesh was implanted in a manner consistent with Defendants' Instructions for Use and in a manner reasonably foreseeable to Defendants. Years after such implantation, Plaintiff suffered a hernia recurrence and the onset of severe groin pain. Plaintiff underwent surgery on June 12, 2020 in which it was discovered that the ProLite mesh had eroded into Plaintiff's bowel and caused a peristomal abscess which had fistulized to the skin. Plaintiff's surgeons had to perform a complex revision of the ileal conduit, mesh excision, and incisional hernia repair.

2. The hernia mesh implanted in Plaintiff by his surgeon was ProLite polypropylene mesh manufactured, promoted, marketed, distributed and sold by Defendants.

3. The ProLite polypropylene mesh caused Plaintiff to suffer permanent injuries, substantial pain and suffering, emotional distress, medical expenses, lost wages and earning capacity, and diminished quality of life.

4. Before Plaintiff underwent hernia repair surgery with ProLite polypropylene mesh, he had no history of these physical and emotional injuries.

5. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that ProLite polypropylene mesh caused the harm and injuries suffered by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of his injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when the injuries were discovered, their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that he had been injured, the cause of the injuries, or the wrongful nature of the conduct causing the injuries, until less than the applicable

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

limitations period before the filing of this complaint. Moreover, Plaintiff was prevented from discovering this information sooner because Defendants misrepresented and concealed, and continue to misrepresent and conceal to the public and the medical profession, the dangers of ProLite polypropylene mesh, as well as the true facts that could have led Plaintiff to discover a cause of action against Defendants for their wrongful conduct.

CLAIMS PURSUANT TO THE WASHINGTON PRODUCT LIABILITY ACT

Pursuant to the Washington Product Liability Act, Chapter 7.72 RCW (the "WPLA), Plaintiff brings the following claims:

1. It was entirely foreseeable and well-known to Defendants that incidents involving its ProLite mesh such as occurred herein would on occasion take place in the ordinary, anticipated and intended use of said devices.

2. Defendants defectively designed, manufactured, assembled and marketed the ProLite mesh in question and so are strictly liable for Plaintiff's damages.

3. The ProLite mesh is defective because Defendants failed to provide adequate warnings and/or instructions regarding the defective conditions and/or the proper use of the device and so are strictly liable for Plaintiff's damages.

4. Defendants breached the implied warranties of merchantability and fitness for a particular purpose, and so are liable for Plaintiff's damages.

5. Defendants were negligent in the design, manufacture, assembly and marketing of the ProLite mesh in question and so are strictly liable for Plaintiff’s damages.

6. Plaintiff’s surgeon, Dr. Robinson, used the ProLite mesh as directed for its intended purpose.

7. At all times herein mentioned, the ProLite mesh used on Plaintiff was defective within the meaning of the WPLA, and Defendants knew of the product defects.

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

8. Moreover, Defendants knew neither Plaintiff nor his surgeon knew or had reason to know of the product defects. Neither Plaintiff nor his surgeon could have discovered the product defects through the exercise of reasonable care and diligent inquiry.

9. The ProLite mesh had not been materially altered or modified prior to being used on Plaintiff.

10. At all times material, Defendants were acting through their employees and/or agents who were within the course and scope of their employment and/or agency for one or all of the Defendants. The Defendants are therefore equally liable under the doctrine of *Respondeat Superior* and/or principles of agency for all actions of their employees and/or agents.

11. Defendants' acts and/or omissions were, separately and collectively with the acts and omissions of other Defendants named herein, a producing and/or proximate cause of Plaintiffs damages.

PUNITIVE DAMAGES ALLEGATIONS

Plaintiff incorporates by reference herein all of the allegations in this Complaint as if fully set forth herein.

1. The acts, conduct and concealment of Defendants, as alleged in this Complaint, were willful, malicious, oppressive and fraudulent. Defendants committed these acts with a conscious disregard for the rights and safety of Plaintiff and other consumers, and for the primary purpose of increasing Defendants' profits from the distribution and sale of ProLite polypropylene mesh. Defendants' outrageous and unconscionable conduct warrants the imposition of punitive damages against Defendants in an amount appropriate to punish and deter such conduct in the future.

2. Before the manufacture, promotion, distribution and sale of ProLite polypropylene mesh to Plaintiff, Defendants knew that it was in a defective condition, and knew that they had made a strategic decision to fraudulently represent and intentionally conceal the significant risks and serious dangers of ProLite polypropylene mesh, as described in this Complaint, and knew that

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

consumers who used ProLite polypropylene mesh for hernia repair would, and did, experience severe physical, mental and emotional injuries. Further, Defendants, through their officers, directors, managers and agents, knew that ProLite polypropylene mesh presented a substantial and unreasonable risk of harm to the public, including Plaintiff. Thus, Defendants unreasonably, maliciously, oppressively and fraudulently subjected consumers of ProLite polypropylene mesh, including Plaintiff, to the risk of serious injury.

3. Despite their knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing the profits of Defendants, knowingly and deliberately failed to remedy the known defects in ProLite polypropylene mesh and failed to warn the public, including Plaintiff, of the serious risk of injury caused by the defects in ProLite polypropylene mesh. Defendants and their officers, directors and managing agents, intentionally proceeded with the manufacture, sale, distribution and marketing of ProLite polypropylene mesh knowing these actions would expose consumers, including Plaintiff, to serious danger in order to advance Defendants' financial interests and increase revenue.

4. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people and was carried on by Defendants with willful and conscious disregard for the rights and safety of Plaintiff and other consumers, thereby entitling Plaintiff to the imposition of punitive damages.

WHEREFORE, Plaintiff prays for judgment against Defendants, as follows:

1. General damages, according to proof;
2. Special damages, according to proof;
3. Loss of earnings and earning capacity, according to proof;
4. Medical expenses, past and future, according to proof;
5. Mental and emotional distress, past and future, according to proof;
6. Punitive damages, according to proof;
7. Costs of suit herein;
8. Pre-judgment and post-judgment interest, as provided by law; and

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax

9. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all counts and as to all issues.

Respectfully submitted this 12th day of January, 2022

DIAMOND MASSONG, PLLC

By: _____
Maria S. Diamond, WSBA No. 13472
1215 Fourth Avenue, Suite 1275
Seattle Washington 98161
(206) 445-1258
Facsimile: (206) 445-1257
maria@diamondmassong.com
Attorney for Plaintiff

DIAMONDMASSONG, PLLC
1215 Fourth Avenue, Suite 1275
Seattle, WA 98161
206.445.1258 Phone • 206.445.1257 Fax